basic requirements applicable to finished devices, including additional requirements for critical devices. This regulation is not intended to apply to manufacturers of components or parts of finished devices, but such manufacturers are encouraged to use appropriate provisions of this regulation as guidelines. Manufacturers of human blood and blood components are not subject to this part, but are subject to Part 606 of this chapter.

(a) *Authority*. This Part 820 is established and promulgated under authority of sections 501, 502, 518, 519, 520(f), and 701(a) of the act (21 U.S.C. 351, 352, 360h, 360i, 360j(f), and 371(a)). The failure to comply with any applicable provisions in Part 820 in the manufacture, packing, storage, or installation of a device renders the device adulterated under section 501(h) of the act. Such a device, as well as the person responsible for the failure to comply, is subject to regulatory action.

(b) *Limitations.* The current good manufacturing practice regulation in Part 820 supplements regulations in other parts of this chapter except where explicitly stated otherwise. In the event it is impossible to comply with applicable regulations both in this part and in other parts of this chapter, the regulations specifically applicable to the device in question shall supersede any other regulations.

(c) *Applicability*. The provisions of Part 820 shall be applicable to any finished device, as defined in this part, intended for human use, that is manufactured, imported, or offered for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(d) *Exemptions or variances.* Any person who wishes to petition for an exemption or variance from any device good manufacturing practice requirement is subject to the requirements of section 520(f)(2) of the act. Petitions for an exemption or variance shall be submitted according to the procedures set forth in §10.30 of this chapter, the Food and Drug Administration's administrative procedures. Guidance is available from the Center for Devices and Radiological Health, Division of Compliance Programs, Manufacturing Quality Assurance Branch (HFZ–332), 1390 Piccard Dr., Rockville, MD 20850; telephone 301–427–1128.

[43 FR 31508, July 21, 1978, as amended at 44 FR 75628, Dec. 21, 1979; 53 FR 11253, Apr. 6, 1988; 55 FR 11169, Mar. 27, 1990]

§ 820.3 Definitions.

(a) *Act* means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201–902, 52 Stat. 1040 et seq., as amended (21 U.S.C. 321–392)).

(b) *Audit* means a documented activity performed in accordance with written procedures on a periodic basis to verify, by examination and evaluation of objective evidence, compliance with those elements of the quality assurance program under review. ''Audit'' does not include surveillance or inspection activities performed for the purpose of conducting a quality assurance program or undertaking complaint investigations or failure analyses of a device.

(c) *Component* means any material, substance, piece, part, or assembly used during device manufacture which is intended to be included in the finished device.

(d) *Control number* means any distinctive combination of letters or numbers, or both, from which the complete history of the manufacture, control, packaging, and distribution of a production run, lot, or batch of finished devices can be determined.

(e) *Critical component* means any component of a critical device whose failure to perform can be reasonably expected to cause the failure of a critical device or to affect its safety or effectiveness.

(f) *Critical device* means a device that is intended for surgical implant into the body or to support or sustain life and whose failure to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury to the user. Critical devices will be identified by the Commissioner after consultation with the Device Good Manufacturing Practice Advisory Committee authorized under section 520(f) of the act, and an illustrative list of critical devices will be available from the Center for Devices and Radiological Health, Food and Drug Administration.

(g) *Critical operation* means any operation in the manufacture of a critical device which, if improperly performed, can be reasonably expected to cause the failure of a critical device or to affect its safety or effectiveness.

(h) *Device history record* means a compilation of records containing the complete production history of a finished device.

(i) *Device master record* means a compilation of records containing the design, formulation, specifications, complete manufacturing procedures, quality assurance requirements, and labeling of a finished device.

(j) *Finished device* means a device, or any accessory to a device, which is suitable for use, whether or not packaged or labeled for commercial distribution.

(k) *Manufacturer* means any person, including any repacker and/or relabeler, who manufactures, fabricates, assembles, or processes a finished device. The term does not include any person who only distributes a finished device.

(l) *Manufacturing material* means any material such as a cleaning agent, mold-release agent, lubricating oil, or other substance used to facilitate a manufacturing process